K023666 Page 1 of 2

JUN 17 2003

RÜSCH INTERNATIONAL
Group Regulatory Affairs
A Subsidiary of Teleflex Incorporated (USA)

Tall Pines Park
Jaffrey, NH 03452
(603) 532-7706
FAX (603) 532-8211 or 6108

510(k) Summary

1. Submitter Name, Address, and Date of Submission:

Rick Lykins
Group RA Manager - US
Rüsch International
Tall Pines Park
Jaffrey, NH 03452
Telephone Number: (603) 532-0204
Fax Number: (603) 532-6179

E-Mail: rlykins@tfx.com

Contact: Same as above

Date of Submission: October 29, 2002

2. Name of the Device, Common, Proprietary (if known), and Classification:

Classification Name: Endoscope and Accessories

Common Name: Cholangiography Catheter

Proprietary Name: Rüsch Guided Cholangiography Catheter

3. Identification of the legally marketed device to which the submitter claims equivalence:

The Rüsch Guided Cholangiography Catheter is substantially equivalent in design and materials to:

- The COOK Unger Endoscopic Cholangiography Set - 510(k) Unknown
- The COOK Franklin Endoscopic Cholangiography Set - 510(k) Unknown
- The COOK Directable Coaxial Catheter Set - K891746

4. Description of the Device:

The Rüsch Guided Cholangiography Catheter is a sterile, single-use device that consists of the following components:

- 10Fr, 30cm, Silicone-Sealed, Curved Polyurethane Guide Catheter with Guide Handle
- 4Fr, 120cm, Curved, Polyvinylchloride Cystic Duct Catheter with Luer-Lock Syringe Connector
  5mm OD, 27cm length, Silicone-Sealed Polyurethane Introduction Tub

The Guide Catheter is provided with a curved tip and a guide handle. The tip is directable toward the desired site by turning the guide handle thus facilitating placement. The direction of the tip is always known as it is in direct relation to the direction flange on the guide handle.

The Cystic Duct Catheter provides centimeter markings at the distal tip to aid in placement.

Each Rüsch Guided Cholangiography Catheter will be provided sterile, by either Gamma Irradiation or Ethylene Oxide, in a clear poly pouch with a medical paper seal. Each device will be individually labeled. The device will then be packaged in a labeled outer cardboard carton. The device will be marketed 5 units per box.

5. Intended Use of the Device:

The Rüsch Guided Cholangiography Catheter is intended for intraoperative cholangiography during laparoscopic cholecystectomy.

6. Summary of Technological Characteristics:

The following technological characteristics are the same as or equivalent to the predicate devices listed above:

Materials:

The materials used in the cystic duct catheter, the guide catheter and the introducer tube have all been used in predicate Rüsch devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 17 2003

Mr. Rick Lykins
Group RA Manager – US
Rüsch International
Tall Pines Park
50 Plantation Drive
JAFFREY NH 03452

Re: K023666
Trade/Device Name: Rüsch Guided Cholangiography Catheter
Regulation Number: 21 CFR §876.5010
Regulation Name: Biliary catheter and accessories
Regulatory Class: II
Product Code: 78 FGE
Dated: March 25, 2003
Received: March 26, 2003

Dear Mr. Lykins:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

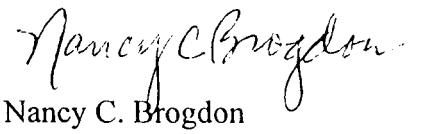
This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,



Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K023666

Device Name: Rüsch Guided Cholangiography Catheter

Indications for Use:

The Rüsch Guided Cholangiography Catheter is intended for intraoperative cholangiography during laparoscopic cholecystectomy.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use ____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

David A. Seymour
(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K023666